

## Total Extractables in PVC

*Extraction System B-811:  
Determination of total extractables in a PVC sample*

Polymeric materials are often used for pharmaceutical purposes, e. g. for packaging, as delivery systems or as manufacturing components. There is the concern that chemical components from polymeric material can leach into these products, especially when they are in contact with liquids. The determination of extractables from polymeric materials is a routine measurement.

### 1. Introduction

Extractables are chemical compounds that migrate from rubber or plastic material under forced conditions (high temperature, solvents). The determination is usually done with a Soxhlet extraction (manual glassware) for 48 h.

This Short Note presents an effective automated Soxhlet extraction method for the determination of extractables in a polyvinyl chloride (PVC) sample. The automated Soxhlet extraction is carried out on the Extraction System B-811. For optimization, the sample is extracted for 2 h resp. 4 h extraction time. Therefore, the extraction time compared to manual Soxhlet extraction is significantly reduced.

Calculation of extractable content follows gravimetrically after the extract has been dried to a constant weight.

### 2. Experimental

Equipment: Extraction System B-811.

Sample: PVC foil with an expected extractable content of about 39 %.

Determination: The sample was weighed into paper thimbles. For the extractions about 1 g of sample (Figure 1) was used.



Figure 1: PVC sample.

The parameters for the extraction on the Extraction System B-811 (Figure 2) are shown in Table 1. For method development the sample was extracted for 2 h resp. 4 h extraction time.



Figure 2: Extraction System B-811.

Table 1: Parameters for the extraction using the Extraction System B-811.

|                    |                                       |
|--------------------|---------------------------------------|
| Solvent            | Diethyl ether                         |
| Extraction method  | Soxhlet standard                      |
| Step 1: Extraction | 120 min resp 240 min, heating level 9 |
| Step 2: Rinsing    | 5 min, heating level 9                |
| Step 3: Drying     | 5 min, heating level 5                |
| Solvent volume     | 120 mL                                |

The extracts were dried to a constant weight in a drying oven at 102°C.

### 3. Results and Discussion

The determined extractable amounts from a PVC sample obtained with the Extraction System B-811 are shown in Table 2.

Table 2: Determined extractables on a PVC sample with the Extraction System B-811; (n = 2).

| Extraction time | Mean value [%] | rsd [%] |
|-----------------|----------------|---------|
| 2 h             | 40.08          | 0.07    |
| 4 h             | 40.11          | 0.45    |

The results demonstrate, that it is possible to reduce the extraction time from 48 h to only 2 h.

### 4. Conclusion

The PVC sample can be extracted with the Extraction System B-811. The results are in the expected range. It was shown that the extraction time could be reduced significantly from 48 h to 2 h.

For more detailed information and safety considerations please refer to the Application Note No. 227/2016.